IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOARD OF REGENTS UNIVERSITY OF TEX and TISSUEGEN, INC.	(AS SYSTEM)	
	Plaintiffs,	C.A. No. 1:18-cv-00392-GBW
v	.)	C.A. No. 1:18-cv-00392-GBW
BOSTON SCIENTIFIC CORPORATION,		
	Defendant.)	

FINAL JURY INSTRUCTIONS (PHASE 1)

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1. GENERAL INSTRUCTIONS

1.1 INTRODUCTION

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case. Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer.

I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating particular testimony and evidence. Then I will explain the positions of the parties and the law you will apply in this case. And last, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

Please listen very carefully to everything I say.

You will have a written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

1.2 JURORS' DUTIES

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you saw and heard in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts.

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on any given issue. It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not guess or speculate, and do not let any bias, sympathy, or prejudice you may feel toward one side or the other influence your decision in any way.

1.3 EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way. The evidence in this case includes only what the witnesses said while they were testifying under oath, including deposition transcript testimony that has been played by video or read to you, the exhibits that I allowed into evidence, matters I have instructed you to take judicial notice of, and the stipulations to which the lawyers agreed.

Certain models, reproductions, charts, summaries, and graphics have been used to illustrate certain evidence and testimony from witnesses. Unless I have specifically admitted them into evidence, these models, reproductions, charts, summaries, and graphics are not themselves evidence, even if they refer to, identify, or summarize evidence, and you will not have these demonstratives in the jury room.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. The arguments of the lawyers are offered solely as an aid to help you in your determination of the facts. Their questions and objections are not evidence. My legal rulings are not evidence. You should not be influenced by a lawyer's objection or by my ruling on that objection. Any of my comments and questions are not evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And, sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. You must completely ignore all of these things. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way. Make your decision based only on the evidence, as I have defined it here, and nothing else.

1.4 DIRECT AND CIRCUMSTANTIAL EVIDENCE

During the preliminary instructions, I told you about "direct evidence" and "circumstantial evidence." I will now remind you what each means.

Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believe him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

1.5 CONSIDERATION OF EVIDENCE

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

1.6 STATEMENTS OF COUNSEL

A further word about statements of counsel and arguments of counsel. The attorneys' statements and arguments are not evidence. Instead, their statements and arguments are intended to help you review the evidence presented.

If you remember the evidence differently from the way it was described by the attorneys, you should rely on your own recollection.

1.7 FACTS ADMITTED

Certain facts from the Complaint and Boston Scientific's Answer to the Complaint have been read to you during this trial. You must treat these facts as having been proved for purposes of this case.

1.8 CREDIBILITY OF WITNESSES

You are the sole judges of each witness's credibility. You may believe everything a witness says, or part of it, or none of it. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witnesses' manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there is evidence tending to prove that the witness testified falsely about some important fact or whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial in person or by deposition testimony played by video or read to you. You have the right to distrust such witness's testimony and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

1.9 EXPERT WITNESSES

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession, or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

1.10 DEPOSITION TESTIMONY

During the trial, certain testimony was presented to you by the playing of video excerpts from a deposition. The deposition testimony may have been edited or cut to exclude irrelevant testimony as the parties have only a limited amount of time to present you with evidence. You should not attribute any significance to the fact that the deposition videos may appear to have been edited.

Deposition testimony is out of court testimony given under oath and is entitled to the same consideration you would give it had the witnesses personally appeared in court.

1.11 DEMONSTRATIVE EXHIBITS

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room for your deliberations. The remainder of the exhibits (including charts, models, reproductions, PowerPoint presentations, and animations) were offered to help illustrate the testimony of the various witnesses. These illustrative exhibits, called "demonstrative exhibits," have not been admitted, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.

1.12 USE OF NOTES

You may have taken notes during trial to assist your memory. As I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency I think to attach undue importance to matters which one has written down. Some testimony which is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence, and are by no means a complete outline of the proceedings or a list of the highlights of the trial.

Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

1.13 BURDENS OF PROOF

In any legal action, facts must be proven by a required standard of evidence, known as the "burden of proof." In a patent case such as this, there are two different burdens of proof that are used. The first is called "preponderance of the evidence." The second is called "clear and convincing evidence." I told you about these two standards of proof during my preliminary instructions to you and I will now remind you what they mean.

Plaintiffs UTBOR and TissueGen assert that Boston Scientific infringes the '296 patent. Plaintiffs UTBOR and TissueGen have the burden of proving their infringement claims by a "preponderance of the evidence." That means Plaintiffs UTBOR and TissueGen had to prove to you, in light of all the evidence, that what they claim is more likely true than not. To say it differently, if you were to put the evidence of Plaintiffs UTBOR and TissueGen and the evidence of Boston Scientific on opposite sides of a scale, the evidence supporting Plaintiffs UTBOR and TissueGen's claims would have to make the scales tip slightly on their side in each instance. If the scale should remain equal or tip in favor of Boston Scientific, you must find for Boston Scientific.

In addition to denying Plaintiffs UTBOR and TissueGen's claims that it infringes, Boston Scientific asserts that the asserted claims of the '296 patent are invalid. A party challenging the validity of a patent—in this instance, Boston Scientific—has the burden to prove that the asserted claims are invalid by clear and convincing evidence. Clear and convincing evidence means evidence that it is highly probable that a fact is true. Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence.

You may have heard of the "beyond a reasonable doubt" burden of proof from criminal cases. That requirement is the highest burden of proof. It does not apply to civil cases and, therefore, you should put it out of your mind.

2. THE PARTIES AND THEIR CONTENTIONS

2.1 THE PARTIES

I will now review for you the parties in this action, and the positions of the parties that you will have to consider in reaching your verdict.

As I have previously told you, the plaintiffs in this case are The Board of Regents of the University of Texas System and TissueGen, Inc. We have referred to the plaintiffs as the Plaintiffs UTBOR and TissueGen. The defendant in this case is Boston Scientific Corporation. We have referred to it as Boston Scientific.

Plaintiff UTBOR is the owner of U.S. Patent Number 6,596,296 and TissueGen holds an exclusive license from Plaintiff UTBOR to the patent. During this case, we have referred the patent by its last three digits, the '296 Patent, often, just the patent-in-suit or the Asserted Patent.

2.2 SUMMARY OF THE ISSUES

You must decide the following issues in this case according to the instructions that I give you:

- 1. Whether Plaintiffs UTBOR and TissueGen have proven by a preponderance of the evidence that Boston Scientific directly infringes one or more of claims 1, 11, 17, and 26 of the '296 patent;
- 2. Whether Plaintiffs UTBOR and TissueGen have proven by a preponderance of the evidence that Boston Scientific Limited [a Boston Scientific subsidiary] directly infringed one or more of claims 1, 11, 17, and 26 of the '296 patent?
- 3. Whether Boston Scientific has proven by clear and convincing evidence that one or more of the asserted claims of the '296 patent is invalid.

3. PATENT INFRINGEMENT CLAIMS

3.1 THE PATENT LAWS

At the beginning of the trial, I gave you some general information about patents and the patent system and a brief overview of the patent laws relevant to this case. I will now give you more detailed instructions about the patent laws that specifically relate to this case. If you would like to review my instructions at any time during your deliberations, you will have your copy available to you in the jury room.

3.2 CLAIM CONSTRUCTION

Before you can decide many of the issues in this case, you will need to understand the role of patent "claims." The patent claims are the numbered sentences at the end of a patent. The claims are important because it is the words of the claims that define what a patent covers. The figures and text in the rest of the patent provide a description and/or examples of the invention and provide a context for the claims, but it is the claims that define the breadth of the patent's coverage. Therefore, what a patent covers depends, in turn, on what each of its claims covers.

To know what a claim covers, a claim sets forth, in words, a set of requirements. Each claim sets forth its requirements in a single sentence. The requirements of a claim are often referred to as "claim elements" or "claim limitations." The coverage of a patent is assessed claim-by-claim. When a thing (such as a product or a process) meets all of the requirements of a claim, the claim is said to "cover" that thing, and that thing is said to "fall" within the scope of that claim. In other words, a claim covers a product or process where each of the claim elements or limitations is present in that product or process.

You will first need to understand what each claim covers in order to decide whether or not there is infringement of the claim and to decide whether or not the claim is invalid. The first step is to understand the meaning of the words used in the patent claim.

This case involves two types of patent claims: independent claims and dependent claims.

An "independent claim" sets forth all of the requirements that must be met in order to be covered by that claim. Thus, it is not necessary to look at any other claim to determine what an independent claim covers. For example, claim 1 of the '296 patent is an independent claim.

The remainder of the claims in the '296 patent are "dependent claims." A dependent claim does not itself recite all of the requirements of the claim but refers to another claim for some of its requirements. In this way, the claim "depends" on another claim. A dependent claim incorporates

all of the requirements of the claim(s) to which it refers. The dependent claim then adds its own additional requirements. Therefore, to determine what a dependent claim covers, it is necessary to look at both the dependent claim and the other claim or claims to which it refers. For example, claim 11 of the '296 patent is a dependent claim that depends from claim 1. A product that meets all of the requirements of both the dependent claim and the claim(s) to which it refers is covered by that dependent claim.

It is my job as a judge to define the terms of the claims and to instruct you about the meaning. It is your role to apply my definitions to the issues that you are asked to decide.

In this case, I have determined the meaning of the following terms of the asserted claims of the '296 patent:

Term	Construction
"first phase"	"the polymer portion of the fiber"
"second phase"	"the discrete drug-containing regions dispersed throughout the fiber"
"immiscible"	"incapable of dissolving into one another"
"fiber"	This term shall have its plain and ordinary meaning, to a person of ordinary skill in the art, which is a "thread-like structure of any length or shape."

Further, the Court has found that the '296 patent is not limited to any specific manufacturing process. You must accept my definition of these words as being correct. It is your job to take these definitions and apply them to the issues that you are deciding, including the issues of infringement and validity.

The beginning portion, also known as the preamble, of a claim often uses the word "comprising." The word "comprising," when used in the preamble, means "including but not limited to" or "containing but not limited to." When "comprising" is used in the preamble, if you

decide that an accused product includes all of the requirements of that claim, the claim is infringed.

This is true even if the accused product contains additional elements.

For any words in the claim for which I have not provided you with a definition, you should apply their ordinary meaning in the field of the '296 patent. You should not take my definition of the language of the claims as an indication that I have a view regarding how you should decide the issues that you are being asked to decide, such as infringement and invalidity. These issues are yours to decide.

3.3 INFRINGEMENT—GENERALLY

I will now instruct you as to the rules you must follow when deciding whether Plaintiffs have proven that Boston Scientific has infringed the '296 patent. You must determine whether UTBOR and TissueGen have proven literal infringement of claims 1, 11, 17, and 26 of the '296 patent.

Infringement is assessed on a claim-by-claim basis. Therefore, there may be infringement of one claim but no infringement of another. There is one exception. If you find that an independent claim is not infringed, there cannot be infringement of any dependent claim that depends directly or indirectly from that claim. On the other hand, if you find that an independent claim has been infringed, you must still separately decide whether the accused products meet the additional requirements of any dependent claim to determine whether that dependent claim has also been infringed.

3.4 DIRECT INFRINGEMENT BY "LITERAL INFRINGEMENT"

To prove direct infringement, UTBOR and TissueGen must prove by a preponderance of the evidence, that Boston Scientific and/or Boston Scientific Limited during the time the '296 patent was in force, (1) made, used, sold, offered for sale within, or imported into the United States a product that meets the requirements of an Asserted Claim and (2) did so without UTBOR's and TissueGen's permission. A patent claim is infringed only if the accused product includes each and every limitation in the Asserted Claim. However, the presence of other features in the accused product beyond the claimed elements does not avoid infringement, as long as every claimed element is present.

4. INVALIDITY

4.1 INVALIDITY—BURDEN OF PROOF

I will now instruct you on the rules you must follow in deciding whether or not Boston Scientific has proven that the Asserted Claims are invalid.

A party challenging the validity of a patent—in this instance, Boston Scientific—has the burden to prove that the asserted claims are invalid by clear and convincing evidence. Clear and convincing evidence means evidence that it is highly probable that a fact is true. Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence.

Like infringement, you must determine whether each asserted claim is invalid on a claimby-claim basis. You must determine separately for each claim whether that claim is invalid. If one claim of a patent is invalid, this does not mean that any other claim is necessarily invalid.

Claims are construed in the same way for determining infringement as for determining invalidity. You must apply the claim language consistently and in the same manner for issues of infringement and for issues of invalidity.

4.2 INVALIDITY—PERSPECTIVE OF ONE OF ORDINARY SKILL IN THE ART

The question of invalidity of a patent claim is determined from the perspective of a person of ordinary skill in the art in the field of the asserted invention as of the time of invention. In deciding the level of ordinary skill, you should consider all the evidence introduced at trial, including:

- (1) the levels of education and experience of persons working in the field;
- (2) the types of problems encountered in the field;
- (3) prior art solutions to those problems;
- (4) rapidity with which innovations are made; and
- (5) the sophistication of the technology.

4.3 INVALIDITY—PRIOR ART

In order for someone to be entitled to a patent, the invention must actually be "new" and not obvious over what came before, which is referred to as the prior art. Prior art is considered in determining whether the Asserted Claims of the '296 patent are anticipated. Prior art may include items that were publicly known or that have been used or offered for sale, or references, such as publications or patents, that disclose the claimed invention or elements of the claimed invention.

U.S. Pat. No. 5,364,627 to Song ("Song") is prior art to the '296 patent.

4.4 INVALIDITY—ANTICIPATION

In order for someone to be entitled to a patent, the invention must actually be "new." If an invention is not new, it is said to be "anticipated." Boston Scientific contends that the asserted claims of the '296 patent are invalid because the claimed inventions are anticipated. Boston Scientific must convince you of this by clear and convincing evidence.

Specifically, Boston Scientific contends that Song anticipates the Asserted Claims of the '296 patent.

Anticipation must be determined on a claim-by-claim basis. Boston Scientific must prove by clear and convincing evidence that all of the requirements of a claim are present in a single piece of prior art. To anticipate the invention, the prior art does not have to use the same words as the claim, but all of the requirements of the claim must have been disclosed and arranged as in the claim. The claim requirements may either be disclosed expressly or inherently—that is, necessarily implied—but must be disclosed in sufficient detail that a person having ordinary skill in the art of the invention, looking at that one reference, could make and use the claimed invention.

Where Boston Scientific is relying on prior art that was not considered by the PTO during examination, you may consider whether that prior art is significantly different and more relevant than the prior art that the PTO did consider. If you decide it is different and more relevant, you may weigh that prior art more heavily when considering whether the challenger has carried its clear-and-convincing burden of proving invalidity.

4.5 INVALIDITY—WRITTEN DESCRIPTION

The patent law contains certain requirements for the part of the patent called the specification. The written description requirement is designed to ensure that the inventor invented the claimed subject matter and was in possession of the full scope of claimed invention as of the patent's effective filing date. Boston Scientific contends that the Asserted Claims of the '296 patent are invalid because the specification of the '296 patent does not contain an adequate written description of the invention.

To succeed, Boston Scientific must show by clear and convincing evidence that a person having ordinary skill in the field reading the patent specification as of the effective filing date of the '296 Patent would not have recognized that it describes the full scope of the invention as it is finally claimed in the Asserted Claims of the '296 Patent. If a patent claim lacks adequate written description, it is invalid.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent as of the effective filing date. The specification must describe the full scope of the claimed invention, including each element thereof, either expressly or inherently. A claimed element is disclosed inherently if a person having ordinary skill in the field as of the effective filing date would have understood that the element is necessarily present in what the specification discloses. It is not sufficient that the specification discloses only enough to make the claimed invention obvious to the person having ordinary skill.

The written description does not have to be in the exact words of the claim. The requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. Adequate written description does not require either examples or an actual reduction to practice of the claimed invention(s). It is not necessary

to describe every compound used in the claimed composition by name or structure in order to satisfy the written description requirement as applied to a group of compounds, as long as the patent includes a sufficient number of representative compounds or a common structural feature, such that a person of ordinary skill in the art would understand, from reading the patent, that the inventor invented the full scope of the claimed invention. However, a mere wish or plan for obtaining the claimed invention(s) is not adequate written description. Rather, the level of disclosure required depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and other considerations appropriate to the subject matter.

5. DELIBERATION AND VERDICT

5.1 INTRODUCTION

Now let me finish up by explaining some things about your deliberation in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

5.2 UNANIMOUS VERDICT

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A form of verdict has been prepared for you. I will review it with you in a moment. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. You will then return to the courtroom and my deputy will read aloud your verdict. Answer each question in the verdict form based on the facts as you find them to be, following the instructions that the Court has given you on the law. Do not decide who you think should win this case and then answer the questions accordingly.

It is proper to add the caution that nothing said in these instructions, and nothing in the form of a verdict, is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is your sole and exclusive duty and responsibility.

5.3 DUTY TO DELIBERATE

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that, your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds. Listen carefully to what the other jurors have to say, and then decide for yourself.

5.4 SOCIAL MEDIA

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, a cell phone, smartphone, iPhone, iPad, blackberry, tablet or computer, the Internet, any Internet service, any text or instant messaging service, any Internet chat room, blog or website such as Facebook, LinkedIn, YouTube, Instagram, WeChat, WhatsApp, SnapChat or Twitter to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

5.5 COURT HAS NO OPINION

Let me finish by repeating something I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.